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SCIENCE POLICY 5: ESTIMATING THE DRINKING WATER COMPONENT OF A DIETARY EXPOSURE ASSESSMENT (12/22/98 DRAFT)

I. EXECUTIVE SUMMARY

The EPA Office of Pesticide Programs (OPP) is proposing to build on its existing policy for estimating pesticide concentrations in drinking water as part of its assessment of dietary exposures to pesticides. The most significant changes being proposed are those that refine existing screening methods for identifying pesticides which may be present in drinking water at levels of concern. These refinements will enable OPP to more accurately estimate the potential risks of pesticides from drinking water exposure to the public and sensitive populations such as infants and children.

For some time the Agency has been using screening models to estimate pesticide concentrations in groundwater and surface water to rule out those food-use pesticides that are not expected to contribute enough exposure via drinking water to result in unacceptable levels of risk. The Agency uses monitoring data, where available and reliable, to refine its assessments in those cases where the use of the screening models does not result in "clearing" (i.e., indicate a low risk) the pesticide from a drinking water perspective. Specifically, OPP proposes to: (1) replace the "farm field pond" scenario in its surface water screening models with a "drinking water reservoir" scenario; (2) incorporate into the model a factor to account for the area surrounding the reservoir that is cropped; (3) develop a second-level (tier 2) screening model for groundwater; (4) evaluate how OPP uses water monitoring data in its drinking water assessment; and (5) continue efforts to obtain additional monitoring of pesticides in drinking water.

The proposed changes are intended to improve EPA's initial screening models by making them capable of producing more accurate estimates of pesticide concentrations in drinking water. In addition, EPA is seeking comment on current approaches to the use of monitoring data in its assessment of drinking water exposure. The Agency particularly seeks comments on the quantity and quality of data that would be appropriate for conducting a drinking water assessments for purposes of tolerance decision-making. Finally, the Agency is soliciting comment on the current approach of back-calculating Drinking Water Levels of Comparison (DWLOC) only after all other exposures from food and residential use are considered.

II. BACKGROUND

A. Why is EPA concerned about including exposure to pesticides in drinking water in its decisions about acceptable levels of pesticides on food?

With the passage of the Food Quality Protection Act (FQPA) in August 1996, Congress directed EPA to consider "all anticipated dietary exposures and all other exposures for which there is reliable information" in determining whether pesticide residues in food are safe. Because a number of pesticides have been found in groundwater and surface water throughout the United States, drinking water should be considered an "anticipated dietary exposure" for certain pesticides. The picture emerging from available federal, state and local water monitoring efforts is complex. Typically a mix of pesticides are detected in water at low levels with seasonal pulses of higher concentrations. Of the major sources of monitoring data that OPP routinely uses – the United States Geological Survey's (USGS) National Water Quality Assessment Program (NAWQA), Toxic Substances Hydrology Program (TSHP), and National Stream Quality Accounting Network (NASQAN), and the EPA's National Pesticide survey – a majority of the streams (up to 95 percent) and half of the wells near agricultural and urban areas contain detectable levels of at least one, and often two or more, pesticides. Most groundwater aquifers and half of the streams investigated by these programs are direct sources of drinking water.

Prior to FQPA, OPP's strategy for managing pesticides which had the potential to contaminate water was to emphasize prevention – requiring mitigation measures such as geographic restrictions on pesticide use (to protect groundwater) and "buffer zones" near water bodies where pesticide use is prohibited (to protect surface water). Only since FQPA has OPP routinely begun to consider exposure to pesticides in drinking water in its dietary risk assessments to decide on acceptable levels of pesticide residues on food (i.e., setting tolerances).

B. *What has been EPA's general process since the passage of the FQPA for including drinking water exposure in its decisions about acceptable levels of pesticides on food?*

August 1996-November 1997

While it developed a more science-based policy for estimating drinking water exposure and for interpreting available monitoring data in the initial months after the enactment of FQPA, OPP used an interim approach which assumed that up to 10% of what it considered acceptable exposure to a pesticide could occur via the drinking water route (PRN 97-1). Therefore, OPP reserved 10% of the "risk cup[1]" for drinking water related risks and allowed food residues and other routes of exposure to take no more than 90% of the "acceptable" risk. This 10% value for drinking water was a default assumption that OPP knew was likely to overestimate actual exposure in many cases, while potentially underestimating actual exposures in some others.

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[1] EPA uses a "risk cup" concept to represent the sum of exposures that, together, do not exceed a maximum safe daily intake. Imagine a cup of fixed capacity (the size of the risk cup depends on how toxic the pesticide is). Each component of pesticide exposure (food, residential exposure, and drinking water for each pesticide use) creates a risk that fills part of the cup. The risk cup for a pesticide may allow for a number of crop-specific uses as long as the aggregate exposure and risk from all of those uses doesn't make the risk cup overflow (i.e., exceed the maximum safe daily intake). Risk cups have been established for short-term exposure (days to weeks) as well as lifetime exposure.

Overview of EPA's Approach Since November 1997

In November of 1997, OPP ceased using the 10% default assumption and formally adopted the following interim process for addressing drinking water exposures.

1. OPP scientists review all available laboratory and field data submitted by the registrant to determine whether a particular pesticide will easily move to groundwater or surface water, will degrade quickly or persist, and will form toxic breakdown products as it degrades.

2. OPP uses pesticide-specific data from these studies in mathematical screening models to estimate pesticide concentrations in water in pesticide use areas. Peer reviews of these models (section II.C) generally supported OPP's view that the estimates coming out of these models are high-end estimates[2] of potential pesticide concentrations in drinking water derived from the upper regions of major watersheds.

3. OPP compares the screening estimates to human health-based "drinking water levels of comparison" (DWLOC)[3], which are derived after first considering all food-related and residential exposures for which EPA has reliable information. This comparison determines whether OPP clears the pesticide from a drinking water perspective or attempts to refine its estimates of pesticide concentrations in drinking water to reflect more representative and realistic conditions. In some cases, the DWLOC may be very low – not because the pesticide is particularly toxic, but because contributions from food-related uses and other pathways of exposure are so great that very little or no room is left in the "risk cup" to allow for any exposure via drinking water. Alternatively, some pesticides (particularly newer pesticides) may have a very high DWLOC solely because they have very few food uses or other uses which result in exposure, leaving a lot of room in the "risk cup."

4. If the model estimates of pesticide concentration in drinking water exceed the DWLOC, OPP attempts to refine its estimate by gathering available water monitoring data for analysis (Section II.D).

5. If monitoring data are not available or are not sufficient for purposes of refining the screening level estimates, OPP makes a risk management decision as to the need for

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[2] "High-end" conditions include applying the compound at the maximum label rate in an environmentally vulnerable setting that is likely to maximize the movement of dissolved pesticides to water. "High-end" refers to a combination of events and conditions such that, taken together, produces conceivable risk greater than 90 percent of the population, but less than the maximally exposed risk.

[3] The Drinking Water Level of Comparison (DWLOC) is the concentration of a chemical in drinking water that would be acceptable as an upper limit in light of *total* aggregate exposure to that chemical from food, water, and non-occupational (residential) sources. It is the difference between the maximum daily intake (the risk cup or reference dose) and the sum of the exposure from food and residential sources. OPP originally used the term "Drinking Water Level of Concern," but felt this term conveyed more of a regulatory concern than is intended. The DWLOC is not a regulatory standard for drinking water, but is the theoretical upper limit of "acceptable" exposure after considering food and residential exposures as sources.

groundwater and/or surface water monitoring and/or risk mitigation. Generally, OPP does not base significant risk management action (e.g., revocation or denial of a tolerance) on screening model estimates.

6. If monitoring data are available and reliable, OPP scientists analyze the data and consult with risk managers as to how the data fit specific risk endpoints being addressed in the human health risk assessment. Appropriate short-term (for acute effects) and/or longer-term average (for chronic effects or cancer) drinking water concentrations are selected. OPP generally does not select the highest reported value from monitoring data; rather, OPP considers the distribution of reported values, compares them to model estimates, and selects value(s) from the high end of the distribution. The values from monitoring data used in the human health risk assessment are usually less than the model estimates but, in a few cases, may be greater than that predicted by OPP's screening models.

7. Estimates of pesticide concentrations in drinking water, derived from monitoring data, are combined with estimates of water consumption to estimate human exposure via drinking water. This estimate of exposure is then added to estimates of food and residential exposure to complete the aggregate exposure assessment.

8. Although rarely sufficient to do so, the monitoring data may be used to produce a regional-based picture of the distribution of measurements.

C. EPA's Use of Screening Models to Estimate Pesticide Concentrations in Drinking Water

1. Surface Water Screening Models

OPP uses two mathematical screening models to rapidly assess whether pesticides are likely or unlikely to occur at significant levels in drinking water derived from surface water[4]. The model GENEEC (GENeric Estimated Environmental Concentrations) provides an initial screening level assessment of pesticide concentrations in surface water while the linked Pesticide Root Zone Model (PRZM) and EXposure Analysis Model System (EXAMS) models provide a more refined screen. GENEEC and PRZM/EXAMS, initially used by OPP for ecological risk assessments, are the only mechanistic models available to OPP for rapidly and cost-effectively producing upper bound estimates of pesticide levels in surface water.

GENEEC uses readily-available pesticide properties to estimate peak and time-averaged pesticide concentrations in a "field pond," 20 million liters (5.3 million gallons) in capacity, located at the edge of a 10-hectare (approximately 25 acres) treated cotton field. The GENEEC model is likely to overestimate pesticide concentrations in drinking water because it assumes that no buffer exists between the pond and the treated field, that runoff exactly equals water losses due to evaporation, and that the pesticide is uniformly mixed throughout the water body. GENEEC

[4] For a more detailed description of these screening models and their use in the drinking water assessments, see the SAP documents (1997 and 1998) listed in the bibliography.

simulates a single pesticide application or series of applications to bare soil followed by a single rainfall event two days after the final application. Depending on the propensity of the pesticide to move into water or stay with the soil, this storm will wash from 0-10% of the pesticide remaining in the top inch of soil at the time of the storm into the pond.

If the surface water estimates using GENEEC do not exceed the DWLOC, then OPP concludes that the pesticide is not expected to pose an unacceptable risk and no further evaluation is necessary. If the GENEEC results indicate a potential concern, then PRZM/EXAMS modeling refines the estimates of potential pesticide levels in surface water by including more pesticide-specific properties, simulating multiple years to reflect climatic variations, and modeling on a crop-specific basis. In comparison to GENEEC, PRZM/EXAMS includes more site-specific information in the scenario details regarding application method and temporal distribution with weather, and better accommodates the peculiarities of individual chemicals. However, it still represents a small pond from which few people would derive their drinking water. Thus, having a body of water which is more reflective of drinking water sources is an important revision to EPA's drinking water exposure assessment.

2. Groundwater Screening Model

OPP developed SCI-GROW (Screening Concentration In GROund Water) as an initial screening model to estimate pesticide concentrations in groundwater under reasonable, vulnerable conditions. SCI-GROW was developed by comparing selected pesticide properties to pesticide concentrations measured in 10 prospective groundwater monitoring studies conducted for OPP by pesticide registrants. The studies were conducted at maximum label application rates under vulnerable conditions (i.e., shallow aquifers with sandy, permeable soils with substantial rainfall and/or irrigation to maximize leaching). The highest three consecutive monthly data points from a selected well in each study were averaged to represent 90-day peak pesticide concentrations. A predictive equation, adjusted for the application rate, was developed by comparing the 90-day peak groundwater concentrations to a pesticide leaching potential index that is based on its persistence in soil (half-life) and affinity to adsorb to soil (soil-water partitioning coefficient).

Using data on pesticide persistence and soil adsorption, and the application rate, SCI-GROW estimates the concentration of a pesticide in shallow groundwater (average depth 15 feet) beneath sandy, highly permeable soils. If the groundwater estimates using SCI-GROW do not exceed the DWLOC, then OPP concludes that the pesticide is not expected to pose an unacceptable risk and no further evaluation is necessary. If the SCI-GROW results indicate a potential concern, OPP currently does not have a tier 2 screening model in place and must rely on available monitoring data for refinements.

D. EPA's Approach to Evaluating and Incorporating Drinking Water Monitoring Data into Human Health Risk Assessments

If the estimates of pesticide concentration in drinking water from PRZM/EXAMS or SCI-GROW do not exceed the DWLOC, then OPP concludes that the pesticide is not expected to pose an unacceptable risk via exposure to drinking water and no further evaluation is necessary.

However, if model estimates do exceed the DWLOC, OPP gathers available water monitoring data and uses it to characterize the anticipated human exposure to the pesticide via drinking water. By the time a pesticide reaches this stage of OPP's review, OPP scientists are operating under the assumption that the pesticide has some potential to reach surface water and/or groundwater and that it has some potential to be present at levels of concern to human health.

Typical sources of monitoring data include USGS's NAWQA, NASQAN, and Toxic Substances Hydrology programs (USGS, 1998), EPA Office of Water's STORET database (US EPA OW, 1998), OPP's Pesticides in Groundwater Data Base (US EPA OPP, 1992), and the National Pesticide Survey (US EPA, 1990). OPP may also seek additional water monitoring data from open literature or state agencies. OPP scientists gather and review as much information as is readily available on how the samples were collected and analyzed, where and when they were collected, and the circumstances surrounding their collection to determine whether existing monitoring data are reliable and relevant.

The availability of adequate temporal and spatial monitoring data can reduce much of the uncertainty associated with models, and can provide a more accurate estimate of the distribution of drinking water concentrations in areas of use. In a few cases, EPA will have "considerable" water monitoring data available for a particular pesticide, including small-scale prospective groundwater monitoring studies and monitoring data from state, local and federal programs. Nevertheless, even when such data are available, they may have been collected in a manner that limits the usefulness for estimating the distribution of drinking water concentrations in areas of use. Therefore, EPA must exercise considerable judgement concerning the best use and interpretation of these data, and how to interpret exposures and risk estimates calculated from them. This is particularly true when trying to characterize exposures from a region where there may be more than one source of water monitoring data.

In evaluating, characterizing and interpreting water monitoring data, OPP scientists attempt to collect as much information as is readily available on the design of the studies. That is, OPP scientists try to determine how the samples were collected and analyzed, why they were collected and where they were collected. To complete the FQPA assessment, OPP scientists review the reliability/validity of the monitoring data and present the range of values reported, the highest values reported, various return frequencies (e.g., 1 in 10 year concentration) the 95th percentile value, and the mean and median values. If OPP has adequate data to produce a regional "picture" of the distribution of reported values, this is completed as well.

Because of the level of variability and uncertainty associated with existing monitoring data, OPP's selection of a value or values to be incorporated into the human health risk assessment can be very difficult. Sometimes valid reported values vary from one region to another by several orders of magnitude. Without having specific information on the history of the use of the pesticide in the sampled area, it is very difficult to fully understand the reasons for these differences. In many cases, the number of "non-detects" greatly exceeds the number of measurements above the limits of detection. While non-detects may result when a pesticide is not likely to move to and persist in water, they may also result when the pesticide is not used in the watershed. EPA often lacks data to verify that reported "non-detects" were in actual areas of use and, thus, has difficulty concluding that the pesticide, when used, is not in fact reaching water frequently enough to be of concern. Further, EPA is not always able to discern whether samples were taken from potential drinking water sources or waters that would be representative of such drinking water sources.

Despite the challenge of analyzing and interpreting these data, OPP has felt it was appropriate to choose a value or values from valid monitoring data to make decisions in the human health risk assessment. Values have been chosen from valid monitoring data even when the data were limited in time or location. Generally, this was done because model-based estimates suggest that DWLOCs may be exceeded. To assume that drinking water exposure is “zero” in the human health risk assessment simply because available, valid monitoring data are highly variable (making it difficult to select a number or numbers) appears counter to OPP’s objective to use the best science available in its decisions to ensure protection of human health. As OPP has gained experience in reviewing and incorporating monitoring data into making tolerance decisions, it has generally chosen “reasonable high end” monitoring values for use in the human health risk assessment. That is, OPP has selected a value on the “high end” of the range rather than the highest measured value.

E. Workshops and Peer Reviews of Screening Models

OPP has sought and obtained external scientific review of its interim approach and of the models it uses to complete screening level assessments from both the FIFRA Scientific Advisory Panel (SAP) and expert panels convened by the International Life Science Institute (ILSI). Most of the external review to date has focused on evaluating the tools and methods used as initial screens to estimate pesticide concentrations in drinking water.

1. International Life Science Institute (ILSI) Risk Science Institute

OPP is working through ILSI to review its current model screening approach and to recommend improvements which could be implemented in the short term to improve the accuracy of its estimates. This cooperative effort is also evaluating how to refine screening level model estimates and how to use and interpret monitoring data. ILSI is a nonprofit foundation established to advance the understanding of scientific issues related to nutrition, food safety, toxicology, and the environment. In October 1997, ILSI convened a working group of scientists with expertise in the fate, transport and occurrence of pesticides in surface water and groundwater to evaluate OPP’s tools and methods for estimating potential concentrations of pesticides in drinking water.

The ILSI working group concluded that (ILSI, 1998):

1. Screening tools are needed to quickly identify pesticides and pesticide uses that are unlikely to contaminate drinking water AND that, in general, the screening models being used by OPP (i.e., GENEEC and SCI-GROW) are of the appropriate type and level of detail to rapidly identify pesticides that are unlikely to be a water problem;

2. Although preliminary evaluations indicate that these models are reliable for screening purposes, further comparisons of model outputs to measured values are needed to confirm that the model estimates are consistently greater than or approximately equal to high-end measurements of drinking water concentrations; and

3. The screening models should be improved so that a higher percent of non-problem pesticides (from a drinking water perspective) can be identified in the initial screen.

The ILSI working group provided recommendations on the types of information on drinking water needed to complete aggregate exposure assessments in its April 2, 1998, report, *Assessment of Methods to Estimate Pesticide Concentrations in Drinking Water Sources* (ILSI, 1998). The ILSI report advised that work toward developing probability distributions (as frequency of exceedance) for peak and long term average drinking water concentrations within a pesticide's use region(s) was needed. Ideally, the estimates of peak and chronic concentrations should be derived from full temporal distributions in actual drinking water. These are the kinds of concentration data which are needed for inclusion with the more refined, probabilistic exposure assessments for residues on food performed using Monte Carlo analysis methods.

2. FIFRA SAP Review

In December 1997 OPP presented its interim methods for estimating exposure to pesticide residues in drinking water to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP). After commending OPP's work, the SAP encouraged OPP to develop a longer term plan for improving tools and methods to produce more refined and accurate estimates of drinking water concentrations. In response to specific questions from OPP, the SAP provided the following important comments:

1. Many panel members agreed that SCI-GROW generates appropriately conservative estimates of pesticide concentrations in drinking water for use in an initial screen. Most believed the estimates needed to be further tested and verified against monitoring data.

2. Nearly all panel members agreed that estimates produced by GENEEC are most likely overly conservative and that some adjustments should be made to account for the percent cropped area around a water body and the percent of that crop treated with the pesticide.

3. Most panel members considered PRZM/EXAMS a reasonable second tier modeling approach for refining estimates generated using GENEEC because of its use of more specific crop, weather, and site geophysical data and more extensive use of pesticide fate and transport data. However, as with GENEEC, many panel members recommended incorporating the percentage of cropped area within the reservoir drainage area in the model. Additionally, the panel was unanimous in recommending a rigorous effort to validate PRZM/EXAMS by (1) comparing model results with data from monitoring studies to determine the limitations and (2) performing a systematic sensitivity analysis of the model input parameters.

4. OPP needs to develop databases and methods that effectively use monitoring both in assessments and model validation. It needs to (1) invest time and resources in the development of geographic information system (GIS) tools related to soil type, crop coverage and water monitoring sampling points; (2) describe and document all variables in its models and methods and better articulate the relative impact of these variables on its drinking water assessment; and (3) compare predictions from its screening models with monitoring data to better understand how these relate.

III. WHAT POLICY CHANGES ARE BEING CONSIDERED?

The long-term goal of OPP is to move toward the use of probabilistic drinking water exposure assessments for tolerance decisions under FQPA. That is, OPP wants to produce information on the number of people likely to be exposed to different levels of pesticide residues in drinking water and use this, along with information on the distribution of consumption values (i.e., the number of people who drink different amounts of water each day), to generate a probabilistic human health risk assessment. However, much remains to be done to develop adequate and reliable probabilistic methods and the data necessary to use these methods. In the meantime, OPP is considering refinements in its existing mathematical screening models and in its use of monitoring data for estimating concentrations of pesticides in drinking water.

Mathematical models allow OPP to rapidly screen pesticides to determine whether the Agency can confidently conclude they are unlikely to occur in drinking water at levels that will result in exceedances of the RfD (when combined with food and residential exposure) or whether the Agency needs more information on them to complete an assessment. While available monitoring data to evaluate the accuracy of these models are scarce, EPA believes these model-based predictions generally overestimate the concentration of pesticides in most drinking water sources due to a combination of factors: (1) the bodies of water modeled are generally farther up in the watershed than the drinking water intakes (and, thus, the pesticide is less diluted than it would be downstream); (2) the estimates do not include the effects of any dilution or treatment that may occur in many, but not all, distribution systems; and (3) the existing models assume the entire watershed is cropped. Hence, for some pesticides, drinking water exposure may appear to contribute to an exposure that would represent an unacceptable dietary risk (alone or in combination with food) even though actual risks to most people would in fact be lower.

For surface water evaluations, EPA plans to replace its current field pond scenario used in screening assessments with an “index” reservoir based on an actual reservoir (Section III.A.1). To more realistically reflect watershed-scale use, the model would also be adjusted for the percentage of the reservoir area that is actually in agricultural production (Section III.A.2). In the longer term, EPA will likely move to a watershed-scale model which more accurately captures basin-area processes and would be more appropriate for drinking water assessments (Section III.A.3). For groundwater evaluations, EPA plans to further test its existing initial (tier 1) screening model and develop a procedure for producing a more refined estimate in those cases where the results of the tier 1 screen suggest concentrations of concern (Section III.A.4).

Reliable and representative data on measured pesticide residues in drinking water are a valuable "real world" assessment tool when available. However, because pesticide concentrations vary greatly in location (some drinking water sources are more vulnerable than others) and time (both seasonally and year-to-year), most existing monitoring data provide little more than a piece of a complex puzzle. OPP is also evaluating ways to better use existing monitoring data and options for obtaining additional monitoring data for pesticides.

A. *How does OPP plan to refine mathematical screening models for use in estimating pesticide concentrations in drinking water?*

OPP plans to continue using mathematical screening models as a part of its tiered approach to assessing the potential exposure to pesticides in drinking water in order to effectively focus resources on the potential problem chemicals. Further, modeling is the only assessment tool currently available to estimate potential concentrations of new pesticides. EPA is considering the following modifications to the models in order to provide a more effective screen that identifies those pesticides for which a potential risk may exist.

1. *The Use of An Index Reservoir in Surface Water Modeling Scenarios*

In July, 1998, OPP presented to the FIFRA SAP a proposed "index" reservoir scenario to replace the "field pond" scenario currently used in its screening models to estimate pesticide concentrations in drinking water derived from surface water. The notion of using a model of an "index" reservoir to screen pesticides is that the chosen reservoir – and its associated characteristics – would become the standard set of conditions by which EPA would judge the potential of a pesticide to contaminate drinking water derived from surface water. The "index" reservoir would be selected from a group of reservoirs that provide drinking water to communities throughout the country. EPA would pick a particular reservoir that has characteristics associated with a higher potential for pesticide contamination of surface water and use those real world characteristics in its mathematical screening model. Because the "index" reservoir models real world characteristics, it is likely to produce more realistic estimates of pesticide concentrations in surface water. Because the "index" reservoir has characteristics that are associated with a higher potential for pesticide contamination of surface water, the model is likely to be protective of other drinking water sources which are less vulnerable to contamination.

Out of an initial list of about 20 possible reservoirs, OPP selected Shipman City Lake in Shipman, Illinois, for evaluation as an "index" reservoir in its screening assessments. This reservoir was selected because it was representative of a number of reservoirs in the central Midwest that are known to be vulnerable to pesticide contamination. These reservoirs tend to be small and shallow with small watersheds, and frequently have Safe Drinking Water Act compliance problems with atrazine, a herbicide widely used on corn grown in these watersheds. Shipman City Lake is 13 acres in area, 9 feet deep, and has a watershed area of 427 acres. Its ratio of drainage to capacity (volume of water in the lake) is approximately 12. As a comparison, the "field pond" currently used has a ratio of 5.

The FIFRA SAP felt the approach to selecting index reservoirs was reasonable, but also recommended additional scientific review and refinements. OPP is considering whether to continue model development with Shipman City Lake[5] or replace it and whether to develop more than one index reservoir. OPP has compiled a list of 82 candidate reservoirs (see list in the docket) of varying sizes that will be screened on the basis of the percentage of the watershed that is cropped (in this case, in corn), the ratio of drainage area to normal reservoir capacity, and the availability of monitoring data on corn herbicides. The selection criteria assume that reservoirs that would be most vulnerable to pesticide contamination by runoff will have a high drainage area in relation to their capacity and a high percentage of that drainage area in crops. The FIFRA SAP recommended that OPP use monitoring data as a component in evaluating the index reservoir approach. Therefore, candidate reservoirs must have adequate monitoring data for evaluation.

The additional index reservoir(s) most likely will be small, similar to Shipman City Lake, although some large reservoirs are also under consideration. The reservoirs will be modeled for atrazine, alachlor, acetochlor, metolachlor and dimethenamid with PRZM, using a scenario that represents the specific watershed. The model results will be evaluated against available monitoring data at each of the reservoirs.

OPP's response to the SAP comments will be submitted to the public docket in January 1999. It is OPP's intent to complete the reservoir selection, scenario development and evaluation of model results with monitoring data by March 30, 1999, and to replace the field pond with the selected "index" reservoir at that time. OPP is soliciting comments on (1) the replacement of the "field pond" scenario with an "index" reservoir; (2) the use of a reservoir similar to Shipman City Lake; and (3) its plan to complete its assessment by March 30, 1999, and move to implementation of the new scenario. OPP will publish its revised policy on this topic in May 1999.

2. Accounting for the Percentage of Area Cropped in the Index Reservoir Models

OPP is working to develop the necessary data bases and Geographical Information System (GIS) tools to enable it to consider the percentage of the area around an index reservoir that is cropped (i.e., the "crop area factor" or "CAF") and, thus potentially treated with a pesticide when it uses its model to predict pesticide levels in a drinking water reservoir. Currently, OPP assumes that the entire area surrounding a body of water is planted with a crop and treated with the pesticide being evaluated. This approach generally results in an overestimate of the amount of pesticide leaving the field and running off into surface water and, therefore, an overestimate of pesticide concentrations in surface water used as drinking water.

OPP used the CAF in the initial index reservoir scenario using Shipman City Lake (July 1998 FIFRA SAP) and found that the resulting modeled concentrations for atrazine were in good

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[5] During the public comment period at the July 1998 SAP, one person expressed concern that Shipman City Lake was impacted by a point source, making it unsuitable for use as an index reservoir. In follow-up investigations, OPP determined that the possible point source was shut down and had not been in operation during the period that monitoring was conducted. Despite that potential concern, the SAP concluded that OPP could continue to develop the index reservoir using Shipman City Lake.

agreement with available monitoring data. However, several substantial uncertainties in the analysis warranted further evaluation and development before a crop area factor is implemented. The CAF was taken from one county included within the Shipman City Lake Watershed. The FIFRA SAP recommended that crop area factors be developed on a watershed rather than a county basis. Because farmers do not grow the same crops on their fields every year, the CAF is likely to differ from year to year. With limited monitoring data and uncertainties in the CAF, more comparisons between pesticide concentrations predicted from models that correct for the crop area and actual monitoring data are needed.

OPP is further evaluating the crop area factor approach using five major and five minor crops. Using 1992 Agricultural Census data, OPP is ranking counties by CAF (since the data are reported on a county basis). For each crop, OPP will use GIS tools to select the small watershed (the 8-digit Hydrologic Unit Code will be the basis for evaluation) which has the highest CAF. The documented method, along with assumptions, limitations, and a list of questions, will be presented to the FIFRA SAP in February 1999. All documentation and questions for the SAP will be submitted to the public docket in January 1999. OPP expects to resolve any issues raised by the SAP and expects to make this revised policy available for a 60-day public comment period by May of 1999. After consideration of public comments, OPP plans to move toward implementation of the CAF no later than October 1999.

The approach that will be presented to the SAP considers using the CAF for a single crop. OPP is soliciting comment on how the CAF should be applied when the pesticide may potentially be used on several crops present in the same watershed. For instance, when a pesticide is used on multiple crops, should the CAF be selected solely on the basis of the highest cumulative CAF? Should other factors (e.g., differing application rates, methods of application, and timing) also be considered? If so, how should they be weighted? Other questions of concern pertain to how OPP should handle changes to the crop area from year to year, crop rotations, and fallow land; how to account for the spatial distribution of the crop within the watershed; and how to apply the CAF to minor-use crops for which data may not be available or may be limited.

It is OPP's intent to implement the index reservoir in advance of the CAF and to incorporate the CAF as it is developed for each crop. However, OPP is soliciting comment on the advisability of this approach. OPP feels strongly that the CAF should not be implemented until it is evaluated against monitoring data. To that end, OPP will be comparing the results of surface water modeling predictions that incorporate the CAF against available monitoring data for the index reservoirs as well as other reservoirs. Should OPP wait until after the CAF is developed to implement the index reservoir?

3. The Use of Watershed-scale Models

OPP completed and presented to the FIFRA SAP in July 1998 its preliminary evaluation of seven watershed-scale surface water models. Further efforts are ongoing to conduct preliminary model validation of watershed-scale models for the White River watershed in Indiana. This model validation effort is expected to provide some preliminary understanding of the relative accuracy of each of these models. OPP expects that one or more of these watershed-scale models will ultimately be used to produce more refined estimates of pesticide concentrations in drinking water for those cases where an unreasonable risk is estimated by the use of a screening level estimate. Whether this would be an additional tier or replace the existing field-scale surface water models will depend on the simplicity and data/resource demands of the watershed model(s).

OPP is soliciting comments on the availability of watershed-scale models and the potential viability of such models as screening tools for drinking water exposure assessments for pesticides.

4. Groundwater Screening Model Approach

OPP will continue to use SCI-GROW as an initial screening tool to determine the potential of a pesticide to contaminate ground water sources of drinking water at concentrations high enough to indicate a potential for risk. On the basis of recommendations of the FIFRA SAP in December 1997 and the experience of OPP in using SCI-GROW as an initial screen for drinking water assessments, OPP will systematically evaluate SCI-GROW against additional groundwater monitoring data and other models. Included in the evaluation will be an assessment of the potential limitations in the predictive capacity of SCI-GROW. For instance, are there certain classes of chemicals or certain environmental fate parameters for which SCI-GROW is not well suited? This evaluation is expected to run parallel to the development of a tier 2 screening model for groundwater. Depending on the outcome of the assessment, some changes in OPP's approach to the initial screening tier for groundwater may occur.

OPP is evaluating models and developing a procedure for a second tier assessment of pesticides in ground water. The Agency has evaluated approximately 50 candidate models and has selected 6 models for detailed evaluation. OPP plans to use data from existing prospective ground water monitoring studies to evaluate the ability of the models to predict pesticide concentrations in ground water. To date, OPP has completed a preliminary evaluation with one data set. A similar evaluation with data sets from at least two other pesticides representing other crops, pesticide groups, use patterns and areas of the country is expected to be completed by October 1999. By December 1999, OPP plans to complete a sensitivity analysis for each model to determine which parameters have greatest impact on results and to develop a protocol describing data needs and quality control for model use. OPP will develop a set of model scenarios similar to those used with PRZM/EXAMS to maximize efficient use of these models by April 2000.

B. What directions are we taking to improve our approach to using monitoring data in estimating pesticide concentrations in drinking water?

OPP will continue efforts to gather and interpret available drinking water monitoring data and to obtain additional monitoring of pesticides in drinking water as individual registration and reregistration decisions are made. Further, OPP is working with Federal government-sponsored water monitoring programs such as the USGS NAWQA Program to ensure that key pesticides and drinking water source waters are covered; OPP is also coordinating pesticide monitoring needs with the U.S. Department of Agriculture (USDA), EPA's Office of Water, and the states.

At the same time, OPP is evaluating how it currently uses monitoring data in drinking water assessments in order to develop standard procedures or guidelines for using such data in FQPA assessments. Currently, OPP includes valid monitoring data in its risk assessment. Monitoring data usually will replace model predictions where the model data indicate a potential problem, even if OPP is unable to determine how representative the monitoring data are. That is, OPP does not always have information to determine whether the available monitoring data are representative of particularly vulnerable drinking water sources. OPP has several concerns regarding this approach:

- Reliance on limited monitoring data that do not necessarily cover the range of use areas may lead to a decision that a pesticide does not pose a risk via the drinking water route under certain conditions when in fact it does. Existing monitoring data may suggest that, on a national basis, the pesticide in question is not occur in drinking water at a frequency of concern. However, in certain vulnerable areas, the pesticide may be found in concentrations high enough to be of toxicological concern.

- A monitoring data set may include non-detects, particularly in a national monitoring program. Non-detects may result when the pesticide occurs in concentrations that are below the limit of detection for the analytical method or when the pesticide is not present at all in the water sample. The absence of the pesticide in water may indicate that the pesticide is not likely to occur in drinking water sources; it may also result when samples are taken in areas where the pesticide is not used or during times of the year when the pesticide is not used. Information needed to evaluate the significance of non-detects is rarely included in the data set.

- The frequency of sample collection in monitoring studies is rarely adequate to capture peak pesticide concentrations or to estimate a reasonable maximum exposure.

- Concentrations of pesticide transformation products which are also of toxicological concern are rarely included in monitoring studies.

- Monitoring data based on raw (i.e., untreated) water samples do not account for removal or dilution of pesticides or, in some cases, the formation of more toxic compounds, that may occur in water treatment. However, because of the variability in treatment processes (which may include no treatment in the case of private wells), data gathered from treated (finished) samples may not be representative of minimal, typical or high-end treatment processes.

- Monitoring data sets often do not provide information on the frequency of occurrence at highly vulnerable sites since they are by definition less common, therefore frequently not sampled in smaller data sets.

- Monitoring data sets often vary in size for different chemicals. The uncertainty is larger for small data sets then larger data sets, generally.

In light of these concerns, OPP is soliciting comments (Section V) on its approach to using monitoring data.

C. How does OPP plan to move to probabilistic drinking water exposure methods?

OPP has developed some crude estimates of the total number of people using different types of source water for drinking water in areas of use. However, because of data and method limitations, it has not yet been able to develop credible estimates of the number of people expected to be exposed to different concentrations of pesticides to incorporate into its assessments.

EPA has entered into a cooperative agreement with the International Life Sciences Institute (ILSI) to advance probabilistic drinking water exposure assessment methodology. ILSI is working to develop long term recommendations for model development and data collection so that estimates of pesticide concentrations in drinking water can be used in probabilistic aggregate exposure analyses in the future. In September 1998, ILSI convened a panel of over a dozen scientists to consider such issues as: (1) What drinking water related data are necessary to use in probabilistic aggregate risk analyses and how can these data be collected; and (2) what role modeling can play in generating information/estimates on pesticide concentration distributions in drinking water sources. Recommendations from the September 1998 meeting are being used by ILSI in a follow-up meeting in December 1998 to develop detailed recommendations on how to collect information that can be used in probabilistic aggregate exposure analysis. ILSI expects to finalize its recommendations in early 1999.

D. How will the proposed changes be incorporated into OPP's drinking water assessments?

OPP expects to implement the "index" reservoir and crop area factors as soon as they become available, but will continue to solicit comments and consider whether or not to incorporate changes based on public comment over time.

The current HED SOP for factoring drinking water exposure into dietary risk assessments will be updated in June 1999 to include the reservoir scenario and will be published for a 60-day comment period. EPA expects that the new SOP, which incorporates the reservoir scenario, will be completed no later than November 1999. A revised SOP that includes the percent cropped area factor (CAF) will be made available no later than December 1999 for comment and will be revised in light of public comment no later than May 2000. The SOP will be updated periodically thereafter as needed.

OPP is also soliciting comments on its approach to developing DWLOCs. Currently, DWLOCs are calculated only after OPP factors in food and any residential exposures. Because DWLOCs are calculated in this manner and then compared to model-based estimates of water concentrations, exceedances of DWLOCs by model estimates can occur even in cases where the drinking water contribution is a very small % of the RfD. Exceedances can lead to use restrictions and requirements to monitor.

IV. HOW WOULD EPA APPLY THE POLICY CHANGES?

EPA intends to implement the index reservoir into the initial screen and begin using it after comments on this notice are reviewed and addressed. As soon as the February 1999 SAP report is completed and comments are addressed, crop area factors will be added to the assessment as they are developed for each crop. The initial screen would thus consist of one standard index reservoir modified by a factor representing the highest agricultural coverage of each crop of concern. If pesticides pass this initial level of screening and there are no monitoring or additional data, then the initial assessment is complete. If monitoring data indicate the potential for higher levels than those predicted by the models, further refinement would be implemented. The proposed policy changes would affect EPA's assessment of surface water levels only, and would be implemented on a crop by crop basis. Multiple uses and the assessment process for ground water will be addressed in the future. It is the intent of these changes to develop a more reliable initial screening process that more efficiently distinguishes between pesticides that have the potential to reach drinking water sources and those that do not. These refinements will be implemented even while EPA continues to develop more probabilistic methods for assessing aggregate drinking water and dietary exposure.

V. REQUEST FOR COMMENTS

EPA is asking for public input on the following aspects of the proposed Drinking Water Exposure Estimate policy:

Surface Water Screening Model Refinements:

- What factors should EPA consider in determining whether to replace the field pond scenario with an index reservoir in surface water screening models?

- What factors should EPA consider in determining whether to use an index reservoir similar to Shipman City Lake for its surface water screening models?

- How should the crop area factor be applied to surface water screening models when the pesticide may potentially be used on several crops present in the same watershed?

- How should OPP address changes to the crop area from year to year, crop rotations, fallow land, and the spatial distribution of the crop within the watershed?

- How should OPP apply the crop area factor to minor-use crops for which data may not be available or may be limited?

- What factors should be considered in implementing the index reservoir? For example, should it be implemented before the crop area factors have been developed and adopted for use in surface water screening models?

- What watershed-scale models are available to provide effective screening tools for drinking water exposure assessments for pesticides?

Incorporating Water Monitoring Data in the Drinking Water Exposure Assessment:

- Under what circumstances should valid monitoring data replace model predictions in a drinking water assessment when the data may not include potentially vulnerable areas?

- How should non-detects be handled in a drinking water assessment?

- What is a workable definition of "reliable" monitoring data for the purpose of conducting a national drinking water assessment? Describe the quantity and quality of data that would be acceptable for the purpose of conducting regional or national drinking water assessments.

- At what scale (i.e., national, regional, or local) should OPP be conducting pesticide assessments in drinking water? What factors are important in determining the scale for assessments?

- OPP currently calculates DWLOCs for drinking water exposure only after contributions from food and residential sources have been considered. Should OPP continue with this current approach or, if not, what approach should OPP consider?

- How should the impact of water treatment processes be incorporated into the drinking water assessment? What information is available on treatment effects on pesticides in water? Should a “default” treatment (i.e., some minimum standard which is employed by most drinking water facilities in the country) be used? If so, what?

VI. BIBLIOGRAPHY

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